

ENGROSSED HOUSE BILL No. 1382

DIGEST OF HB 1382 (Updated April 1, 2009 10:42 am - DI 104)

Citations Affected: IC 5-10; IC 12-15; IC 27-8; IC 27-13; noncode.

Synopsis: Insurance coverage for clinical trials. Requires coverage for certain services related to cancer clinical trials under a state employee health plan, the state Medicaid program, a policy of accident and sickness insurance, and a health maintenance organization contract.

Effective: July 1, 2009.

Welch, Brown C, Brown T

(SENATE SPONSORS — GARD, SIPES, BECKER, MILLER)

January 13, 2009, read first time and referred to Committee on Public Health. February 10, 2009, amended, reported — Do Pass. February 12, 2009, read second time, amended, ordered engrossed. February 13, 2009, engrossed. February 16, 2009, read third time, passed. Yeas 95, nays 0.

SENATE ACTION

February 19, 2009, read first time and referred to Committee on Health and Provider Services.
April 2, 2009, amended, reported favorably — Do Pass.



First Regular Session 116th General Assembly (2009)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in this style type, and deletions will appear in this style type.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or *this style type* reconciles conflicts between statutes enacted by the 2008 Regular Session of the General Assembly.

ENGROSSED HOUSE BILL No. 1382

A BILL FOR AN ACT to amend the Indiana Code concerning insurance.

Be it enacted by the General Assembly of the State of Indiana:

1	SECTION 1. IC 5-10-8-15 IS ADDED TO THE INDIANA CODE
2	AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
3	1, 2009]: Sec. 15. (a) As used in this section, "care method" means
4	the use of a particular drug or device in a particular manner.
5	(b) As used in this section, "clinical trial" means a Phase I, II,
6	III, or IV research study:
7	(1) that is conducted:
8	(A) using a particular care method to prevent, diagnose, or
9	treat a cancer for which:
10	(i) there is no clearly superior, noninvestigational
11	alternative care method; and
12	(ii) available clinical or preclinical data provides a
13	reasonable basis from which to believe that the care
14	method used in the research study is at least as effective
15	as any noninvestigational alternative care method;
16	(B) in a facility where personnel providing the care method

to be followed in the research study have:

17







1	(i) received training in providing the care method;
2	(ii) expertise in providing the type of care required for
3	the research study; and
4	(iii) experience providing the type of care required for
5	the research study to a sufficient volume of patients to
6	maintain expertise; and
7	(C) to scientifically determine the best care method to
8	prevent, diagnose, or treat the cancer; and
9	(2) that is approved or funded by one (1) of the following:
10	(A) A National Institutes of Health institute.
11	(B) A cooperative group of research facilities that has an
12	established peer review program that is approved by a
13	National Institutes of Health institute or center.
14	(C) The federal Food and Drug Administration.
15	(D) The United States Department of Veterans Affairs.
16	(E) The United States Department of Defense.
17	(F) The institutional review board of an institution located
18	in Indiana that has a multiple project assurance contract
19	approved by the National Institutes of Health Office for
20	Protection from Research Risks as provided in 45 CFR
21	46.103.
22	(G) A research entity that meets eligibility criteria for a
23	support grant from a National Institutes of Health center.
24	(c) As used in this section, "covered individual" means an
25	individual entitled to coverage under a state employee health plan.
26	(d) As used in this section, "routine care cost" means the cost of
27	medically necessary services related to the care method that is
28	under evaluation in a clinical trial. The term does not include the
29	following:
30	(1) The health care service, item, or investigational drug that
31	is the subject of the clinical trial.
32	(2) Any treatment modality that is not part of the usual and
33	customary standard of care required to administer or support
34	the health care service, item, or investigational drug that is
35	the subject of the clinical trial.
36	(3) Any health care service, item, or drug provided solely to
37	satisfy data collection and analysis needs that are not used in
38	the direct clinical management of the patient.
39	(4) An investigational drug or device that has not been
40	approved for market by the federal Food and Drug
41	Administration.
42	(5) Transportation, lodging, food, or other expenses for the



1	notions on a family member or companion of the notices that
1	patient or a family member or companion of the patient that
2	are associated with travel to or from a facility providing the
3 4	clinical trial. (6) A service, item, or drug that is provided by a clinical trial
5	
	sponsor free of charge for any new patient.
6	(7) A service, item, or drug that is eligible for reimbursement
7	from a source other than a covered individual's policy of
8	accident and sickness insurance, including the sponsor of the
9	clinical trial.
10	(e) As used in this section, "state employee health plan" means
11	one (1) of the following:
12	(1) A self-insurance program established under section 7(b) of
13	this chapter to provide group health coverage.
14	(2) A contract with a prepaid health care delivery plan that is
15	entered into or renewed under section 7(c) of this chapter.
16	(f) A state employee plan that provides coverage for basic health
17	care services must include coverage for routine care costs that are
18	incurred in the course of a clinical trial if the plan would provide
19	coverage for the same routine care costs not incurred in a clinical
20	trial.
21	(g) The coverage that must be included under this section is
22	subject to the terms, conditions, restrictions, exclusions, and
23	limitations that apply generally under the state employee plan,
24	including treatment rendered by participating and
25	nonparticipating providers.
26	(h) This section does not require the state employee plan to offer
27	coverage for clinical trial services rendered by a participating
28	provider under the state employee plan.
29	(i) This section does not prohibit the state employee plan from
30	offering coverage for clinical trial services by a participating
31	provider.
32	(j) This section does not require reimbursement for services that
33	are performed in a clinical trial by a nonparticipating provider at
34	the same rate as those performed by a participating provider.
35	(k) This section does not create a cause of action against an
36	insurer or health maintenance organization for any harm to an
37	individual resulting from a clinical trial.
38	SECTION 2. IC 12-15-5-9.2 IS ADDED TO THE INDIANA CODE
39	AS A NEW SECTION TO READ AS FOLLOWS [EFFECTIVE JULY
40	1, 2009]: Sec. 9.2. (a) As used in this section, "care method" means
41	the use of a particular drug or device in a particular manner.

(b) As used in this section, "clinical trial" means a Phase I, II,



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1	III, or IV research study:	
2	(1) that is conducted:	
3	(A) using a particular care method to prevent, diagnose, or	
4	treat a cancer for which:	
5	(i) there is no clearly superior, noninvestigational	
6	alternative care method; and	
7	(ii) available clinical or preclinical data provides a	
8	reasonable basis from which to believe that the care	
9	method used in the research study is at least as effective	
10	as any noninvestigational alternative care method;	
11	(B) in a facility where personnel providing the care method	
12	to be followed in the research study have:	
13	(i) received training in providing the care method;	
14	(ii) expertise in providing the type of care required for	
15	the research study; and	
16	(iii) experience providing the type of care required for	
17	the research study to a sufficient volume of patients to	
18	maintain expertise; and	
19	(C) to scientifically determine the best care method to	
20	prevent, diagnose, or treat the cancer; and	
21	(2) that is approved or funded by one (1) of the following:	
22	(A) A National Institutes of Health institute.	
23	(B) A cooperative group of research facilities that has an	
24	established peer review program that is approved by a	
25	National Institutes of Health institute or center.	
26	(C) The federal Food and Drug Administration.	
27	(D) The United States Department of Veterans Affairs.	
28	(E) The United States Department of Defense.	V
29	(F) The institutional review board of an institution located	
30	in Indiana that has a multiple project assurance contract	
31	approved by the National Institutes of Health Office for	
32	Protection from Research Risks as provided in 45 CFR	
33	46.103.	
34	(G) A research entity that meets eligibility criteria for a	
35	support grant from a National Institutes of Health center.	
36	(c) As used in this section, "routine care cost" means the cost of	
37	medically necessary services related to the care method that is	
38	under evaluation in a clinical trial. The term does not include the	
39	following:	
40	(1) The drug or device that is under evaluation in a clinical	
41	trial.	
12	(2) Items or services that are:	



in the direct clinical management of an individual enrolled in a clinical trial; (B) customarily provided at no cost by a research sponsor to an individual enrolled in a clinical trial; or (C) provided solely to determine eligibility of an individual for participation in a clinical trial. (d) The Medicaid program must include coverage for routine care costs that are incurred in the course of a clinical trial if the program would provide coverage for the same routine care costs not incurred in a clinical trial. (e) The coverage that must be included under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the Medicaid program, including treatment rendered by participating and nonparticipating providers. (f) This section does not require the Medicaid program to offer		
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17 (f) This section does not require the Medicaid program to offer	including treatment rendered by participating and	15
•	nonparticipating providers.	16
coverage for clinical trial services rendered by a participating	(f) This section does not require the Medicaid program to offer	17
6 T T T T T T T T T T T T T T T T T T T	coverage for clinical trial services rendered by a participating	18
19 provider under the Medicaid program.	provider under the Medicaid program.	19
20 (g) This section does not prohibit the Medicaid program from	(g) This section does not prohibit the Medicaid program from	20
offering coverage for clinical trial services by a participating	offering coverage for clinical trial services by a participating	21
provider.	provider.	22
23 (h) This section does not require reimbursement for services	(h) This section does not require reimbursement for services	23
that are performed in a clinical trial by a nonparticipating	that are performed in a clinical trial by a nonparticipating	24
provider at the same rate as those performed by a participating	provider at the same rate as those performed by a participating	25
provider.	provider.	26
27 (i) Under a patient informed consent document, no party is	(i) Under a patient informed consent document, no party is	27
28 liable for damages associated with the treatment provided during	liable for damages associated with the treatment provided during	28
any phase of the clinical trial.	any phase of the clinical trial.	29
30 SECTION 3. IC 27-8-25 IS ADDED TO THE INDIANA CODE AS	SECTION 3. IC 27-8-25 IS ADDED TO THE INDIANA CODE AS	30
31 A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY	A NEW CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY	31
32 1, 2009]:	-	32
33 Chapter 25. Coverage for Care Related to Clinical Trials	Chapter 25. Coverage for Care Related to Clinical Trials	33
Sec. 1. As used in this chapter, "care method" means the use of	· · · · · · · · · · · · · · · · · · ·	34
a particular drug or device in a particular manner.	<u>*</u> ′	
Sec. 2. As used in this chapter, "clinical trial" means a Phase I,	•	36
37 II, III, or IV research study:	• '	
38 (1) that is conducted:	•	
39 (A) using a particular care method to prevent, diagnose, or		
40 treat a cancer for which:		
41 (i) there is no clearly superior, noninvestigational		
42 alternative care method; and	· · · · · · · · · · · · · · · · · · ·	



1	(ii) available clinical or preclinical data provides a
2	reasonable basis from which to believe that the care
3	method used in the research study is at least as effective
4	as any noninvestigational alternative care method;
5	(B) in a facility where personnel providing the care method
6	to be followed in the research study have:
7	(i) received training in providing the care method;
8	(ii) expertise in providing the type of care required for
9	the research study; and
10	(iii) experience providing the type of care required for
11	the research study to a sufficient volume of patients to
12	maintain expertise; and
13	(C) to scientifically determine the best care method to
14	prevent, diagnose, or treat the cancer; and
15	(2) that is approved or funded by one (1) of the following:
16	(A) A National Institutes of Health institute.
17	(B) A cooperative group of research facilities that has an
18	established peer review program that is approved by a
19	National Institutes of Health institute or center.
20	(C) The federal Food and Drug Administration.
21	(D) The United States Department of Veterans Affairs.
22	(E) The United States Department of Defense.
23	(F) The institutional review board of an institution located
24	in Indiana that has a multiple project assurance contract
25	approved by the National Institutes of Health Office for
26	Protection from Research Risks as provided in 45 CFR
27	46.103.
28	(G) A research entity that meets eligibility criteria for a
29	support grant from a National Institutes of Health center.
30	Sec. 3. As used in this chapter, "covered individual" means an
31	individual entitled to coverage under a policy of accident and
32	sickness insurance.
33	Sec. 4. As used in this chapter, "policy of accident and sickness
34	insurance" has the meaning set forth in IC 27-8-5-1. The term does
35	not include the following:
36	(1) Accident only, credit, dental, vision, Medicare, Medicare
37	supplement, long term care, or disability income insurance.
38	(2) Coverage issued as a supplement to liability insurance.
39	(3) Automobile medical payment insurance.
40	(4) A specified disease policy.
41	(5) A limited benefit health insurance policy.
42	(6) A short term insurance plan that:



1	(A) may not be renewed; and
2	(B) has a duration of not more than six (6) months.
3	(7) A policy that provides a stipulated daily, weekly, or
4	monthly payment to an insured during hospital confinement,
5	without regard to the actual expense of the confinement.
6	(8) Worker's compensation or similar insurance.
7	(9) A student health insurance policy.
8	Sec. 5. As used in this chapter, "routine care cost" means the
9	cost of medically necessary services related to the care method that
0	is under evaluation in a clinical trial. The term does not include the
.1	following:
2	(1) The health care service, item, or investigational drug that
3	is the subject of the clinical trial.
4	(2) Any treatment modality that is not part of the usual and
.5	customary standard of care required to administer or support
6	the health care service, item, or investigational drug that is
7	the subject of the clinical trial.
8	(3) Any health care service, item, or drug provided solely to
9	satisfy data collection and analysis needs that are not used in
20	the direct clinical management of the patient.
21	(4) An investigational drug or device that has not been
22	approved for market by the federal Food and Drug
23	Administration.
24	(5) Transportation, lodging, food, or other expenses for the
25	patient or a family member or companion of the patient that
26	are associated with travel to or from a facility providing the
27	clinical trial.
28	(6) A service, item, or drug that is provided by a clinical trial
29	sponsor free of charge for any new patient.
30	(7) A service, item, or drug that is eligible for reimbursement
31	from a source other than a covered individual's policy of
32	accident and sickness insurance, including the sponsor of the
3	clinical trial.
4	Sec. 6. (a) A policy of accident and sickness insurance must
55	include coverage for routine care costs that are incurred in the
56	course of a clinical trial if the policy of accident and sickness
57	insurance would provide coverage for the same routine care costs
8	not incurred in a clinical trial.
19	(b) The coverage that must be included under this section is
10	subject to the terms, conditions, restrictions, exclusions, and
1	limitations that apply generally under the policy of accident and
12	sickness insurance, including treatment rendered by participating



1	and nonparticipating providers.
2	(c) This section does not require an insurer to offer coverage for
3	clinical trial services rendered by a participating provider under
4	a policy of accident and sickness insurance.
5	(d) This section does not prohibit an insurer from offering
6	coverage for clinical trial services by a participating provider.
7	(e) This section does not require reimbursement for services
8	that are performed in a clinical trial by a nonparticipating
9	provider at the same rate as those performed by a participating
.0	provider.
1	Sec. 7. This chapter does not create a cause of action against an
2	insurer for any harm to an individual resulting from a clinical
.3	trial.
4	SECTION 4. IC 27-13-7-20.2 IS ADDED TO THE INDIANA
.5	CODE AS A NEW SECTION TO READ AS FOLLOWS
6	[EFFECTIVE JULY 1, 2009]: Sec. 20.2. (a) As used in this section,
7	"care method" means the use of a particular drug or device in a
. 8	particular manner.
9	(b) As used in this section, "clinical trial" means a Phase I, II,
20	III, or IV research study:
21	(1) that is conducted:
22	(A) using a particular care method to prevent, diagnose, or
23	treat a cancer for which:
24	(i) there is no clearly superior, noninvestigational
2.5	alternative care method; and
26	(ii) available clinical or preclinical data provides a
27	reasonable basis from which to believe that the care
28	method used in the research study is at least as effective
29	as any noninvestigational alternative care method;
50	(B) in a facility where personnel providing the care method
1	to be followed in the research study have:
32	(i) received training in providing the care method;
3 34	(ii) expertise in providing the type of care required for
	the research study; and
55 56	(iii) experience providing the type of care required for the research study to a sufficient volume of patients to
57	maintain expertise; and
88	(C) to scientifically determine the best care method to
19	prevent, diagnose, or treat the cancer; and
10	(2) that is approved or funded by one (1) of the following:
1	(A) A National Institutes of Health institute.
12	(R) A cooperative group of research facilities that has an



1	established peer review program that is approved by a
2	National Institutes of Health institute or center.
3	(C) The federal Food and Drug Administration.
4	(D) The United States Department of Veterans Affairs.
5	(E) The United States Department of Defense.
6	(F) The institutional review board of an institution located
7	in Indiana that has a multiple project assurance contract
8	approved by the National Institutes of Health Office for
9	Protection from Research Risks as provided in 45 CFR
10	46.103.
11	(G) A research entity that meets eligibility criteria for a
12	support grant from a National Institutes of Health center.
13	(c) As used in this section, "routine care cost" means the cost of
14	medically necessary services related to the care method that is
15	under evaluation in a clinical trial. The term does not include the
16	following:
17	(1) The health care service, item, or investigational drug that
18	is the subject of the clinical trial.
19	(2) Any treatment modality that is not part of the usual and
20	customary standard of care required to administer or support
21	the health care service, item, or investigational drug that is
22	the subject of the clinical trial.
23	(3) Any health care service, item, or drug provided solely to
24	satisfy data collection and analysis needs that are not used in
25	the direct clinical management of the patient.
26	(4) An investigational drug or device that has not been
27	approved for market by the federal Food and Drug
28	Administration.
29	(5) Transportation, lodging, food, or other expenses for the
30	patient or a family member or companion of the patient that
31	are associated with travel to or from a facility providing the
32	clinical trial.
33	(6) A service, item, or drug that is provided by a clinical trial
34	sponsor free of charge for any new patient.
35	(7) A service, item, or drug that is eligible for reimbursement
36	from a source other than a covered individual's policy of
37	accident and sickness insurance, including the sponsor of the
38	clinical trial.
39	(d) An individual or a group contract that provides for basic
40	health care services must include coverage for routine care costs
41	that are incurred in the course of a clinical trial if the contract
42	would provide coverage for the same routine care costs not



1	incurred in a clinical trial.	
2	(e) The coverage that must be included under this section is	
3	subject to the terms, conditions, restrictions, exclusions, and	
4	limitations that apply generally under the individual or a group	
5	contract, including treatment rendered by participating and	
6	nonparticipating providers.	
7	(f) This section does not require a health maintenance	
8	organization to offer coverage for clinical trial services rendered	
9	by a participating provider under an individual or a group	
10	contract.	
11	(g) This section does not prohibit a health maintenance	
12	organization from offering coverage for clinical trial services by a	
13	participating provider.	
14	(h) This section does not require reimbursement for services	
15	that are performed in a clinical trial by a nonparticipating	
16	provider at the same rate as those performed by a participating	
17	provider.	
18	(i) This section does not create a cause of action against a health	
19	maintenance organization for any harm to an individual resulting	
20	from a clinical trial.	
21	SECTION 5. [EFFECTIVE JULY 1, 2009] (a) IC 5-10-8-15, as	
22	added by this act, applies to a state employee health plan that is	
23	established, entered into, issued, delivered, amended, or renewed	
24	after June 30, 2009.	
25	(b) IC 12-15-5-9.2, as added by this act, applies to a Medicaid	
26	risk based managed care contract that is entered into, delivered,	
27	amended, or renewed after June 30, 2009.	
28	(c) IC 27-8-25, as added by this act, applies to a policy of	V
29	accident and sickness insurance that is issued, delivered, amended,	
30	or renewed after June 30, 2009.	
31	(d) IC 27-13-7-20.2, as added by this act, applies to an individual	
32	contract or a group contract that is entered into, delivered,	
33	amended, or renewed after June 30, 2009.	



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(e) This SECTION expires July 1, 2014.

COMMITTEE REPORT

Mr. Speaker: Your Committee on Public Health, to which was referred House Bill 1382, has had the same under consideration and begs leave to report the same back to the House with the recommendation that said bill be amended as follows:

Page 1, line 9, delete "or another serious or life threatening disease".

Page 2, line 9, delete "or other serious or" and insert "; and

- (2) that is approved or funded by one (1) of the following:
 - (A) A National Institutes of Health institute.
 - (B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.
 - (C) The federal Food and Drug Administration.
 - (D) The United States Department of Veterans Affairs.
 - (E) The United States Department of Defense.
 - (F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.
 - (G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.".

Page 2, delete lines 10 through 31.

Page 3, delete lines 12 through 15, begin a new paragraph and insert:

- "(f) A state employee plan that provides coverage for basic health care services may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the plan would provide coverage for the same routine care costs not incurred in a clinical trial.
- (g) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the state employee plan, including treatment rendered by participating and nonparticipating providers.
- (h) This section does not require the state employee plan to offer coverage for clinical trial services rendered by a participating provider under the state employee plan.
- (i) This section does not prohibit the state employee plan from offering coverage for clinical trial services by a participating provider.
 - (j) This section does not require reimbursement for services that







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are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.

- (k) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.
- (1) This section does not create any private right or cause of action for or on behalf of any new patient against a party that issues the state employee plan.".
- Page 3, line 24, delete "or another serious or life threatening disease".

Page 3, line 41, delete "or other serious or" and insert "; and".

Page 3, delete line 42.

Page 4, delete lines 1 through 21, begin a new line block indented and insert:

- "(2) that is approved or funded by one (1) of the following:
 - (A) A National Institutes of Health institute.
 - (B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.
 - (C) The federal Food and Drug Administration.
 - (D) The United States Department of Veterans Affairs.
 - (E) The United States Department of Defense.
 - (F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.
 - (G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.".

Page 4, delete lines 36 through 38, begin a new paragraph and insert:

- "(d) The Medicaid program may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the program would provide coverage for the same routine care costs not incurred in a clinical trial.
- (e) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the Medicaid program, including treatment rendered by participating and nonparticipating providers.
- (f) This section does not require the Medicaid program to offer coverage for clinical trial services rendered by a participating









provider under the Medicaid program.

- (g) This section does not prohibit the Medicaid program from offering coverage for clinical trial services by a participating provider.
- (h) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.
- (i) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.
- (j) This section does not create any private right or cause of action for or on behalf of any new patient against the state.".

Page 4, line 39, delete "(e)" and insert "(k)".

Page 5, line 10, delete "or another serious or life threatening disease".

Page 5, line 27, delete "or other serious or" and insert "; and".

Page 5, delete lines 28 through 42, begin a new line block indented and insert:

- "(2) that is approved or funded by one (1) of the following:
 - (A) A National Institutes of Health institute.
 - (B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.
 - (C) The federal Food and Drug Administration.
 - (D) The United States Department of Veterans Affairs.
 - (E) The United States Department of Defense.
 - (F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.
 - (G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.".

Page 6, delete lines 1 through 7.

Page 6, delete lines 32 through 42, begin a new line block indented and insert:

- "(1) The health care service, item, or investigational drug that is the subject of the clinical trial.
- (2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is











the subject of the clinical trial.

- (3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.
- (4) An investigational drug or device that has not been approved for market by the federal Food and Drug Administration.
- (5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility providing the clinical trial.
- (6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.
- (7) A service, item, or drug that is eligible for reimbursement from a source other than a covered individual's policy of accident and sickness insurance, including the sponsor of the clinical trial.".

Page 7, delete lines 1 through 2, begin a new paragraph and insert:

- "Sec. 6. (a) A policy of accident and sickness insurance may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the policy of accident and sickness insurance would provide coverage for the same routine care costs not incurred in a clinical trial.
- (b) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the policy of accident and sickness insurance, including treatment rendered by participating and nonparticipating providers.
- (c) This section does not require an insurer to offer coverage for clinical trial services rendered by a participating provider under a policy of accident and sickness insurance.
- (d) This section does not prohibit an insurer from offering coverage for clinical trial services by a participating provider.
- (e) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating provider at the same rate as those performed by a participating provider.
- Sec. 7. (a) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.
- (b) This section does not create any private right or cause of action for or on behalf of any new patient against an insurer that











issues a policy of accident and sickness insurance.".

Page 7, line 11, delete "or another serious or life threatening disease".

Page 7, line 28, delete "or other serious or" and insert "; and".

Page 7, delete lines 29 through 42, begin a new line block indented and insert:

- "(2) that is approved or funded by one (1) of the following:
 - (A) A National Institutes of Health institute.
 - (B) A cooperative group of research facilities that has an established peer review program that is approved by a National Institutes of Health institute or center.
 - (C) The federal Food and Drug Administration.
 - (D) The United States Department of Veterans Affairs.
 - (E) The United States Department of Defense.
 - (F) The institutional review board of an institution located in Indiana that has a multiple project assurance contract approved by the National Institutes of Health Office for Protection from Research Risks as provided in 45 CFR 46.103.
 - (G) A research entity that meets eligibility criteria for a support grant from a National Institutes of Health center.".

Page 8, delete lines 23 through 26, begin a new paragraph and insert:

- "(d) An individual or a group contract that provides for basic health care services may not exclude coverage for routine care costs that are incurred in the course of a clinical trial if the contract would provide coverage for the same routine care costs not incurred in a clinical trial.
- (e) The coverage that may not be excluded under this section is subject to the terms, conditions, restrictions, exclusions, and limitations that apply generally under the individual or a group contract, including treatment rendered by participating and nonparticipating providers.
- (f) This section does not require a health maintenance organization to offer coverage for clinical trial services rendered by a participating provider under an individual or a group contract.
- (g) This section does not prohibit a health maintenance organization from offering coverage for clinical trial services by a participating provider.
- (h) This section does not require reimbursement for services that are performed in a clinical trial by a nonparticipating







provider at the same rate as those performed by a participating provider.

- (i) Under a patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of the clinical trial.
- (j) This section does not create any private right or cause of action for or on behalf of any new patient against a health maintenance organization that issues an individual or a group contract.".

and when so amended that said bill do pass.

(Reference is to HB 1382 as introduced.)

BROWN C, Chair

Committee Vote: yeas 7, nays 0.

HOUSE MOTION

Mr. Speaker: I move that House Bill 1382 be amended to read as follows:

Page 9, delete lines 11 through 18.

(Reference is to HB 1382 as printed February 10, 2009.)

WELCH

COMMITTEE REPORT

Madam President: The Senate Committee on Health and Provider Services, to which was referred House Bill No. 1382, has had the same under consideration and begs leave to report the same back to the Senate with the recommendation that said bill be AMENDED as follows:

Page 2, delete lines 30 through 39, begin a new line block indented and insert:

- "(1) The health care service, item, or investigational drug that is the subject of the clinical trial.
- (2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is

EH 1382—LS 6698/DI 97+









the subject of the clinical trial.

- (3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.
- (4) An investigational drug or device that has not been approved for market by the federal Food and Drug Administration.
- (5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility providing the clinical trial.
- (6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.
- (7) A service, item, or drug that is eligible for reimbursement from a source other than a covered individual's policy of accident and sickness insurance, including the sponsor of the clinical trial.".

Page 3, line 5, delete "may not exclude" and insert "must include". Page 3, line 9, delete "may not be excluded" and insert "must be included".

Page 3, line 23, delete "Under a patient informed consent document, no party is" and insert "This section does not create a cause of action against an insurer or health maintenance organization for any harm to an individual resulting from a clinical trial.".

Page 3, delete lines 24 through 28.

Page 3, line 29, delete "IC 12-15-5-9" and insert "IC 12-15-5-9.2".

Page 3, line 31, delete "Sec. 9." and insert "Sec. 9.2.".

Page 4, line 41, delete "may not exclude" and insert "must include".

Page 5, line 3, delete "may not be excluded" and insert "must be included".

Page 5, delete lines 21 through 25.

Page 7, line 30, delete "may not" and insert "must include".

Page 7, line 31, delete "exclude".

Page 7, line 35, delete "may not be excluded" and insert "must be included".

Page 8, line 7, delete "(a) Under a patient informed consent document, no party" and insert "This chapter does not create a cause of action against an insurer for any harm to an individual resulting from a clinical trial.".

Page 8, delete lines 8 through 12.

Page 8, line 13, delete "IC 27-13-7-20" and insert "IC 27-13-7-20.2".

EH 1382-LS 6698/DI 97+











Page 8, line 15, delete "20." and insert "20.2.".

Page 9, delete lines 15 through 24, begin a new line block indented and insert:

- "(1) The health care service, item, or investigational drug that is the subject of the clinical trial.
- (2) Any treatment modality that is not part of the usual and customary standard of care required to administer or support the health care service, item, or investigational drug that is the subject of the clinical trial.
- (3) Any health care service, item, or drug provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient.
- (4) An investigational drug or device that has not been approved for market by the federal Food and Drug Administration.
- (5) Transportation, lodging, food, or other expenses for the patient or a family member or companion of the patient that are associated with travel to or from a facility providing the clinical trial.
- (6) A service, item, or drug that is provided by a clinical trial sponsor free of charge for any new patient.
- (7) A service, item, or drug that is eligible for reimbursement from a source other than a covered individual's policy of accident and sickness insurance, including the sponsor of the clinical trial.".

Page 9, line 26, delete "may not exclude" and insert "must include". Page 9, line 30, delete "may not be excluded" and insert "must be included".

Page 10, line 4, delete "Under a patient informed consent document, no party is" and insert "This section does not create a cause of action against a health maintenance organization for any harm to an individual resulting from a clinical trial.".

Page 10, delete lines 5 through 10.

Page 10, line 15, delete "IC 12-15-5-9," and insert "IC 12-15-5-9.2,".











Page 10, line 21, delete "IC 27-13-7-20," and insert "IC 27-13-7-20.2,".

and when so amended that said bill do pass.

(Reference is to HB 1382 as reprinted February 13, 2009.)

MILLER, Chairperson

Committee Vote: Yeas 7, Nays 0.

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